

# SUPPLEMENTAL PROTOCOL CHECKLIST

## PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Section	Notes	√
<b>RISKS</b>	Physical	
	Social	
	Psychological	
<b>METHODS TO MINIMIZE RISKS</b>		
<b>ANTICIPATED BENEFITS</b>		
<b>RISK/BENEFIT RATIO</b>		
<b>VULNERABLE POPULATIONS</b>	Pregnant Women, Fetuses, <i>in vitro</i> Fertilization	
	Prisoners	
	Children	
<b>IMPLEMENTATION/ DOCUMENTATION OF INFORMED CONSENT</b>		
<b>JUSTIFICATION FOR WAIVER/ALTERATION OF INFORMED CONSENT</b>		
<b>JUSTIFICATION FOR WAIVER/ALTERATION OF <i>DOCUMENTATION</i> OF INFORMED CONSENT</b>		
<b>IMPLEMENTATION/ DOCUMENTATION OF ASSENT (CHILDREN)</b>		
<b>IMPLEMENTATION/ DOCUMENTATION OF PARENTS'/GUARDIANS' PERMISSION</b>		

Section	Notes	√
<b>PROTECTION OF PRIVACY AND CONFIDENTIALITY</b>	Privacy of Individual	
	Confidentiality of Data	
<b>ASSURANCE/ CERTIFICATE OF CONFIDENTIALITY</b>	Assurance of Confidentiality (308(d) PHS Act; protects both individuals and institutions)	
	Certificate of Confidentiality (301(d) PHS Act; protects only individuals	
<b>EXTRA COSTS</b>		
<b>REIMBURSEMENTS/ INCENTIVES</b>		
<b>APPENDIX MATERIAL (RELEVANT SUPPLEMENTARY MATERIALS)</b>		

# SUPPLEMENTAL GUIDE FOR PROTOCOL CHECKLIST

## PROTECTION OF HUMAN RESEARCH PARTICIPANTS

***Description of risks (physical, social, psychological) to the individual or group. Include methods to minimize risks:*** Define the nature, magnitude, probability, and duration of potential harms that a person may receive by participating in this research. Describe steps that have been taken to minimize risks, including the use of sound research design and by using procedures already being performed on the participant or other routine procedures that will be provided to the participant.

***Description of anticipated benefits to the research participant:*** Discuss benefits to research participants resulting from the research. Describe the steps that have been, or will be, taken to maximize benefits.

***Description of the potential risk to anticipated benefit ratio:*** Justify that the potential risk are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result from the research.

***Justification for involving vulnerable participant populations:*** If study participants include a special or vulnerable population, such as children, prisoners or mentally incompetent, provide justification for their use in terms of the purpose of the research.

***Procedures for implementing and documenting informed consent:*** Describe procedures for informing participants and methods to document consent.

***Justification for waiver or alteration of informed consent:*** If informed consent will not be obtained or will be altered, describe the justification for waiver. The justification must address the four criteria for waiving or altering consent: 1) the research involves no more than minimal risk to the participants, 2) the waiver or alternation will not adversely affect the rights and welfare of the participants, 3) the research could not practicably be carried out without the waiver or alteration, and 4) whenever appropriate, the participants will be provided with additional pertinent information after participation.

***Justification for waiver of documentation of informed consent:*** If written informed consent will not be obtained, provide justification for obtaining consent through other means. The justification must address one of the two criteria for waiving documentation: 1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality or 2) that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. If the first criterion is used, describe the procedures to ensure that participants' regarding documentation linking them to the research will be ascertained and honored.

***Description of procedures for implementing and documenting the assent process of children:*** Describe procedures for informing children and methods to document assent.

***Description of procedures for implementing and documenting parents' or guardians' consent:*** Describe procedures for informing participants and methods to document parental permission.

***Provisions for protecting privacy/confidentiality:*** Explain provisions for protecting study participants from being identified either directly or indirectly. If for any reason data identifying subjects will be published or released to persons outside of the project, explain why this is necessary.

***Statement about need or lack of need for assurance or certificate of confidentiality:*** This refers to formal assurances and certificates of confidentiality.

***Statement of extra costs to participants due to involvement in the study:*** Self explanatory.

***Description and justification of reimbursements or incentives that will be used:*** Self explanatory.

***If the study involves special populations, such as pregnant women, fetuses, prisoners, children or human in vitro fertilization, include a section that specifically addresses the requirements of HHS regulations 45 CFR 46.***

- 1. If fetuses are included, see Subpart B of 45 CFR 46.***
- 2. If pregnant women are participants, see Subpart B of 45 CFR 46.***
- 3. If human in vitro fertilization is used, see Subpart B of 45 CFR 46.***
- 4. If prisoners are participants, see Subpart C of CFR 45 CFR 46.***
- 5. If children are participants, see Subpart D of CFR 45 CFR 46.***

## **APPENDIX MATERIALS**

***Include all relevant supplementary materials. All materials for use by participants must be written in lay language.***

***Announcements/advertisements, notification letters, videos, scripts, other information for participants:*** Recruiting literature should include the name and address of the project officer, the purpose of the research and the selection criteria for inclusion in the study, a straightforward and simple description of the study, potential risks and benefits, method of compensation for time and inconvenience, the location of the research, sponsoring agencies, the person to contact for further information, an estimate of the time per session and total time of participation.

***Data collection forms***

***Questionnaires, interview schedules, observation plans, focus group discussion guides, etc.***

***Coding guidelines and definitions of themes/variables***

***Medical records and / or other abstraction forms***

***Request and authorization for release of medical records***

***Manuals for training study personnel.***

## *Consent and assent forms*